

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC. and
JAZZ PHARMACEUTICALS IRELAND
LIMITED,

Plaintiffs,

v.

AVADEL PHARMACEUTICALS PLC,
AVADEL US HOLDINGS, INC., AVADEL
SPECIALTY PHARMACEUTICALS, LLC,
AVADEL LEGACY PHARMACEUTICALS,
LLC, AVADEL MANAGEMENT
CORPORATION and AVADEL CNS
PHARMACEUTICALS LLC,

Defendants.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz Pharmaceuticals” or “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC (collectively “Avadel” or “Defendants”), allege as follows:

Nature of the Action

1. This is an action for patent infringement and for a declaratory judgement of patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.* and 28 U.S.C. §§ 2201 and 2202, arising from Avadel’s filing of a New Drug Application (“NDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market

a sodium oxybate drug product prior to the expiration of United States Patent Nos. 11,077,079 (the “’079 patent” or “the patent-in-suit”).

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

4. On information and belief, Defendant Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland, having a principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. On information and belief, Avadel Pharmaceuticals plc is in the business of, *inter alia*, developing, manufacturing, marketing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

5. On information and belief, Defendant Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel US Holdings, Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its

affiliates, including Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

6. On information and belief, Avadel US Holdings, Inc. is a wholly-owned subsidiary of Avadel Pharmaceuticals plc.

7. On information and belief, Defendant Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Specialty Pharmaceuticals, LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

8. On information and belief, Defendant Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Legacy Pharmaceuticals, LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

9. On information and belief, Defendant Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Management Corporation is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals LLC.

10. On information and belief, Defendant Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel CNS Pharmaceuticals LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation.

11. On information and belief, Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are wholly-owned subsidiaries of Avadel US Holdings, Inc.

12. On information and belief, following any FDA approval of their NDA for a sodium oxybate product, Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel

Management Corporation, and Avadel CNS Pharmaceuticals LLC will work in concert with one another to make, use, offer to sell, and/or sell the product that is the subject of their NDA for a sodium oxybate product throughout the United States, and/or import such a product into the United States.

Jurisdiction and Venue

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. On information and belief, Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware because Avadel Pharmaceuticals plc has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. On information and belief, Avadel Pharmaceuticals plc manufactures, markets, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

15. On information and belief, Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware because Avadel US Holdings, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel US Holdings, Inc. manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel US Holdings, Inc. is

registered to do business in Delaware (business identification number 5123065) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

16. On information and belief, Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Specialty Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 6507288) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

17. On information and belief, Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Legacy Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC manufactures, markets, imports,

offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 4886228) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

18. On information and belief, Avadel Management Corporation is subject to personal jurisdiction in Delaware because Avadel Management Corporation has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel Management Corporation manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Management Corporation is registered to do business in Delaware (business identification number 6201113) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

19. On information and belief, Avadel CNS Pharmaceuticals LLC is subject to personal jurisdiction in Delaware because Avadel CNS Pharmaceuticals LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably

anticipate being haled into court in Delaware. Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC is registered to do business in Delaware (business identification number 7734658) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

20. On information and belief, Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are agents and/or alter egos of one another and work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

21. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with Delaware, including, but not limited to, the above-described contacts, and the actions on behalf of Defendants in connection with their NDA seeking FDA approval to commercially market a sodium oxybate drug product, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with Delaware law.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

23. On August, 3 2021, the USPTO duly and lawfully issued the '079 patent entitled, "GHB formulation and method for its manufacture." A copy of the "'079 patent" is attached hereto as Exhibit A.

Background

24. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the '079 patent cover, *inter alia*, methods of use and administration of pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patent-in-suit.

Acts Giving Rise to This Suit

25. Pursuant to Section 505(b)(2) of the FFDCA, Avadel filed an NDA ("Avadel's NDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of a sodium oxybate product ("Avadel's Proposed Product"), before the patent-in-suit expires.

26. On December 16, 2020, Avadel announced the submission of its NDA to the FDA. On information and belief, on February 26, 2021, the FDA notified Avadel of formal acceptance of Avadel's NDA with an assigned Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.¹

¹ See Avadel's 2020 Annual Report at p. 7 (available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm>)

27. Avadel has identified its Proposed Product using the code name FT218.²

28. Avadel has published data comparing the pharmacokinetic properties of Avadel's Proposed Product with twice-nightly sodium oxybate (*i.e.*, XYREM®).³

29. Avadel owns U.S. Patent No. 10,272,062 ("Avadel's '062 patent") entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics," attached hereto as Exhibit B.

30. On information and belief, Avadel's published data concerning the pharmacokinetic properties of Avadel's Proposed Product correspond to the Examples of Avadel's '062 patent.

31. On information and belief, Avadel's Proposed Product is an embodiment of the claims of Avadel's '062 patent.

32. On information and belief, the formulations of gamma-hydroxybutyrate described in Avadel's '062 patent are preferably supplied in sachets.⁴

33. On information and belief, Avadel's Proposed Product, FT218, will be made available in unit dose-sachets at 4.5 gram, 6 gram, 7.5 gram, and 9 gram doses.⁵

34. On information and belief, the sachets containing the formulations described in Avadel's '062 patent are meant to be opened and their contents mixed with water to provide the nightly dose of gamma-hydroxybutyrate.⁶

² See *id.*

³ Seiden, et al., *Pharmacokinetics of FT218, a Once-Nightly Sodium Oxybate Formulation in Healthy Adults*, Clin. Ther. 2021 Feb 22; S0149-2918(21)00044-8; doi: 10.1016/j.clinthera.2021.01.017, attached hereto as Exhibit C.

⁴ See Avadel's '062 patent at 44:7-17 ("The modified release formulation of gamma-hydroxybutyrate is preferably supplied in sachets or stick-packs comprising a particulate formulation.")

⁵ See Avadel's March 8, 2018 Q1 2018 Earnings Call Transcript, attached hereto as Exhibit D.

35. On information and belief, Avadel's Proposed Product, FT218, is covered by Jazz Pharmaceuticals' '079 patent.

36. On information and belief, Avadel has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Avadel's Proposed Product prior to expiration of the patent-in-suit.⁷ Avadel recently confirmed that it has "accelerated" its launch planning for its Proposed Product.⁸

37. On information and belief, Avadel continues to seek approval of its NDA from the FDA and, if approved, intends to commercially have Avadel's Proposed Product manufactured for marketing and sale in the United States.

Count for Infringement of the '079 Patent

38. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

39. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '079 patent.

40. Avadel's NDA has been pending before the FDA since at least December 16, 2020, the date that Avadel announced the submission of its NDA to the FDA.

41. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior

⁶ See Avadel's '062 patent at 31:55-65; *id.* at 44:7-17; *see also* Exhibit C at 3.

⁷ See Avadel's 2020 Annual Report at pp. 18, 29, 48 (available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm>); *see also* Avadel's March 9, 2021 Q4 2020 Earnings Call Transcript, attached hereto as Exhibit E.

⁸ See Avadel's May 10, 2021 Q1 2021 Earnings Call Transcript, attached hereto as Exhibit F.

to the expiration of the '079 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

42. There is a justiciable controversy between the parties hereto as to the infringement of the '079 patent.

43. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '079 patent.

44. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '079 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

45. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '079 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '079 patent and knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the '079 patent.

46. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will contributorily infringe one or more claims of the '079 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel's Proposed Product is especially adapted for a use that infringes one or

more claims of the '079 patent and that there is no substantial non-infringing use for Avadel's Proposed Product.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Avadel's infringement of the '079 patent is not enjoined.

48. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel's Proposed Product prior to expiration of the '079 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the '079 patent.

49. Plaintiffs do not have an adequate remedy at law.

50. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Avadel has infringed the patent-in-suit by submitting its NDA for its sodium oxybate drug product;

(B) A Judgment be entered that Avadel has infringed, and that Avadel's making, using, selling, offering to sell, and/or importing Avadel's Proposed Product will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of Avadel's NDA for its sodium oxybate drug product be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Avadel and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, selling, offering to sell, and/or importing Avadel's Proposed Product until after the

expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Avadel, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of Avadel's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Avadel has committed any acts with respect to the methods claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Avadel engages in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Avadel's Proposed Product prior to the expiration of the patent-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

August 4, 2021

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

*Attorneys for Plaintiffs Jazz Pharmaceuticals,
Inc. and Jazz Pharmaceuticals Ireland Limited*